

Brainstorm Issues 2017 Letter to Shareholders

HACKENSACK, N.J. and PETACH TIKVAH, Israel, Dec. 29, 2017 /[PRNewswire](#)/ -- BrainStorm Cell Therapeutics Inc. (NASDAQ: BCLI), a leading developer of adult stem cell therapeutics for neurodegenerative diseases, today issued a Letter to Shareholders from its President and CEO, Chaim Lebovits

Dear Valued Shareholders,

This past year was an extraordinary success for BrainStorm Cell Therapeutics. A key accomplishment was the enrollment of the first US patients in the Phase 3 clinical trial of NurOwn® for the treatment of amyotrophic lateral sclerosis (ALS). In addition to our clinical success, we have further developed our manufacturing capabilities in many ways, including validating the cryopreservation process. Financially, we received additional non-dilutive grants from the California Institute for Regenerative Medicine (CIRM) as well as the Israel Innovation Authority. In addition, we have further strengthened our executive team with new key appointments.

In October, we enrolled the first patients in the randomized, double-blind, placebo-controlled multi-dose Phase 3 clinical trial of NurOwn® for the treatment of ALS. Our Phase 3 trial builds upon the promising efficacy demonstrated in our Phase 2 randomized US trial, the first ALS study data to highlight the restoration of patient function.

As the most advanced stem cell therapy in development for the treatment of ALS, our Phase 3 trial will enroll approximately 200 patients at six leading clinical sites in the U.S. The NurOwn® phase 3 trial patient population will focus on the patient sub-groups which demonstrated superior outcomes in the Phase 2 ALS clinical trial. The primary outcome measure will be the ALSFR-S score responder analysis, a score that measures a patient's ability to perform tasks that are affected by ALS. We expect interim safety data in mid 2018 and top-line data in late 2019. The phase 3 trial will also expand upon phase 2 biomarkers to further evaluate their potential to predict ALS disease progression and NurOwn® treatment response.

The pivotal phase 3 NurOwn® trial is being supported by a \$16 million non-dilutive grant from the California Institute for Regenerative Medicine (CIRM). In addition, for the tenth consecutive year, we have received non-dilutive grants from the Israel Innovation Authority to further support the development of NurOwn®, including a \$2.1 million grant in 2017.

We met and exceeded expectations in 2017 on the manufacturing and product development front. As an important milestone for potential commercialization, in early 2017 our NurOwn® cryopreservation process was validated for the Phase 3 clinical study for treatment of ALS. Additionally, to further expand our manufacturing capabilities, we contracted the City of Hope's Center for Biomedicine and Genetics, California, to produce clinical supplies of NurOwn® for our Phase 3 trial.

We continue to explore strategic partnerships to advance NurOwn's clinical development and maximize its market potential. In 2017 we signed a Memorandum of Understanding (MOU) to explore the possibility of making NurOwn® available to ALS patients under provision of the MOH Hospital Exemption regulation with Tel Aviv Sourasky Medical Center.

In addition, this year we expanded our patent portfolio by obtaining an additional US patent for BrainStorm's NurOwn® technology for the treatment of ALS and Parkinson's disease. This move further protects our technology and is a result of BrainStorm's ongoing development and clinical successes.

In parallel to our NurOwn® successes, we strengthened our executive team and board of directors. We added three senior members to our executive team: Ralph Z. Kern, MD, MHSc joined Brainstorm in a dual role as Chief Operating Officer and Chief Medical Officer, starting in March. In August, Mary Kay Turner joined as Vice President of Patient Advocacy and Government Affairs. Eyal Rubin joined early November as Chief Financial Officer, responsible for corporate finance and accounting. These individuals were chosen for their deep neuroscience experience, significant industry expertise and long track record of industry achievements.

Our Board of Directors was strengthened in February with the addition of June S. Almenoff, M.D., Ph.D., FACP, and Arturo O. Araya, M.A., M.B.A. Their vast experience in drug development and commercialization, and cell and gene therapy are valuable assets to our company, particularly at this important time.

This year, in addition to support enrollment in the Phase 3 ALS clinical trial, we are also looking to advance BrainStorm's pipeline in other neurodegenerative diseases, based on strong preclinical data in Parkinson's disease and Multiple Sclerosis.

In closing, management is dedicated to achieving our primary goals to deliver value for our shareholders, to develop transformative cell therapies for ALS and other severe neurodegenerative diseases, and to be the leader in this field. We have accomplished much in the past year but there is no doubt in our mind that our best days are ahead of us. Thank you for your continued interest in and commitment to support Brainstorm.

Please do not hesitate to contact us directly with any additional questions; we can be reached at info@brainstorm-cell.com

Sincerely,
Chaim Lebovits
President and CEO
BrainStorm Cell Therapeutics Inc.

View original content with multimedia: <http://www.prnewswire.com/news-releases/brainstorm-issues-2017-letter-to-shareholders-300576006.html>



SOURCE BrainStorm Cell Therapeutics Inc.

<https://ir.brainstorm-cell.com/2017-12-29-Brainstorm-Issues-2017-Letter-to-Shareholders>